

# PATENT COOPERATION TREATY

From the:  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:  
  
Cullen & Co  
GPO Box 1074  
BRISBANE QLD 4001

## PCT

### NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing  
(day/month/year) **31 MAR 2006**

Applicant's or agent's file reference  
**031392PC/KF**

#### IMPORTANT NOTIFICATION

International application No.  
**PCT/AU2004/001800**

International filing date (day/month/year)  
**21 December 2004**

Priority date (day/month/year)  
**23 December 2003**


Applicant

**PROGEN INDUSTRIES LIMITED et al**

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.
4. **REMINDER**  
  
The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).  
  
Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.  
  
For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.  
  
The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

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**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)  
(PCT Article 36 and Rule 70)

|   |  |  |                       |
|---|--|--|-----------------------|
| Applicant's or agent's file reference<br><b>031392PC/KF</b>   | <b>FOR FURTHER ACTION</b>  |  | See Form PCT/IPEA/416 |
| International application No.<br><b>PCT/AU2004/001800</b>   | International filing date ( <i>day/month/year</i> )<br><b>21 December 2004</b> | Priority date ( <i>day/month/year</i> )<br><b>23 December 2003</b> |                       |
| International Patent Classification (IPC) or national classification and IPC<br><div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">Int. Cl.<br/><b>C07H 5/10 (2006.01)</b></div> <div style="text-align: center;"><b>A61P 7/00 (2006.01)</b></div> <div style="text-align: center;"><b>A61P 43/00 (2006.01)</b></div> </div> <div style="text-align: right; margin-top: 5px;">(continued in Supplemental Box)</div> |  |  |                       |
| Applicant<br><b>PROGEN INDUSTRIES LIMITED et al</b>   |  |  |                       |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of **7** sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☒ (sent to the applicant and to the International Bureau) a total of **5** sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☒ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

|                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

|   |  |
|---|--|
| Date of submission of the demand<br><b>6 June 2005</b>  | Date of completion of this report<br><b>24 March 2006</b>  |
| Name and mailing address of the IPEA/AU<br><b>AUSTRALIAN PATENT OFFICE</b><br><b>PO BOX 200, WODEN ACT 2606, AUSTRALIA</b><br>E-mail address: <b>pct@ipaaustralia.gov.au</b><br>Facsimile No. <b>(02) 6285 3929</b> | Authorized Officer:<br><div style="text-align: center; margin-top: 10px;"> <br/> <b>O.L. CHAI</b><br/> Telephone No. <b>(02) 6283</b> </div> |

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/001800

**Box No. I**      **Basis of the report**

## 1. With regard to the language, this report is based on:

☒ The international application in the language in which it was filed☐ A translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:☐ international search (under Rules 12.3(a) and 23.1 (b))☐ publication of the international application (under Rule 12.4(a))☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:☐ the international application as originally filed/furnished☒ the description:

pages 1-2, 5-50 as originally filed/furnished

pages\* 3, 4 received by this Authority on 17 February 2006 with the letter of 17 February 2006

pages\* received by this Authority on with the letter of

☒ the claims:

pages as originally filed/furnished

pages\* as amended (together with any statement) under Article 19

pages\* 51-53 received by this Authority on 17 February 2006 with the letter of 17 February 2006

pages\* received by this Authority on with the letter of

☐ the drawings:

pages as originally filed/furnished

pages\* received by this Authority on with the letter of

pages\* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.3. ☐ The amendments have resulted in the cancellation of:☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/figs☐ the sequence listing (*specify*):☐ any table(s) related to the sequence listing (*specify*):4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).☐ the description, pages☒ the claims, Nos. 7-8☐ the drawings, sheets/figs☐ the sequence listing (*specify*):☐ any table(s) related to the sequence listing (*specify*):

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/AU2004/001800**Box No. III** Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos: 1, 3 (in part)

because:

☐ the said international application, or the said claims Nos.

relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos.  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos.  
are so inadequately supported by the description that no meaningful opinion could be formed (*specify*)

☒ no international search report has been established for said claim Nos. 1, 3 (in part)

☐ A meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ Furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ Furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ Pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.

☐ A meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/001800

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

|                               |                  |     |
|-------------------------------|------------------|-----|
| Novelty (N)                   | Claims 1-6, 9-16 | YES |
|                               | Claims           | NO  |
| Inventive step (IS)           | Claims 1-6, 9-16 | YES |
|                               | Claims           | NO  |
| Industrial applicability (IA) | Claims 1-6, 9-16 | YES |
|                               | Claims           | NO  |

## 2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this opinion:

- D1 WO 1985/000973
- D2 US 4459293
- D3 WO 2003/038054
- D4 Derwent Abstract Accession No 2000-100762/09
- D5 Derwent Abstract Accession No 2001-337999/36
- D6 Derwent Abstract Accession No 2000-116716/10
- D7 WO 1993/024506
- D8 WO 1997/018222
- D9 Derwent Abstract Accession No 96-116981/12
- D10 US 5700918
- D11 Chemical Abstracts AN 140:314439
- D12 Chemical Abstracts AN 141:54554
- D13 Chemical Abstracts AN 138:82903
- D14 Chemical Abstracts AN 133:267051
- D15 Chemical Abstracts AN 131:322848
- D16 Chemical Abstracts AN 129:107414

D11 and D12 are published after the priority date of the application. These documents may become relevant if the priority date of the application is found to be invalid at a later date.

Novelty (N) & Inventive Step (IS)

D1 discloses substituted phenyl-1-thio(poly-O-sulfo)- $\alpha$ (or  $\beta$ )-D-glucopyranosides, cation salts thereof and their use as modulators of the complement system involved with inflammation, coagulation, fibrinolysis, antibody-antigen reactions and other metabolic processes.

D2 discloses bis-[ $\beta$ -D-glucopyranosyl-1-thio (or sulfinyl or sulconyl)-arylene sulfate derivatives, the cation salts thereof, useful as modulators of the complement system involved with inflammation, coagulation, fibrinolysis, antibody-antigen reactions and other metabolic processes.

D4 discloses sulfated galactose compounds (I) and their pharmaceutical preparation.

(continued in Supplemental Box)

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

International application No.

**PCT/AU2004/001800****Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of: International Patent Classification (IPC)

Int. Cl.

|                               |                             |                             |
|-------------------------------|-----------------------------|-----------------------------|
| <i>A61K 31/70</i> (2006.01)   | <i>A61P 7/02</i> (2006.01)  | <i>C07H 11/04</i> (2006.01) |
| <i>A61K 31/7012</i> (2006.01) | <i>A61P 29/00</i> (2006.01) | <i>C07H 13/12</i> (2006.01) |
| <i>A61K 31/7016</i> (2006.01) | <i>A61P 31/00</i> (2006.01) | <i>C07H 15/04</i> (2006.01) |
| <i>A61K 31/7028</i> (2006.01) | <i>A61P 35/00</i> (2006.01) | <i>C07H 15/18</i> (2006.01) |

Action Date: 24 March 2006

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of: item 4 of Box No. I

The subject matter of claims 7-8 goes beyond the disclosure in the international application as filed. Substituting one or more sulfate groups of the compounds of claim 1 with an alternative charged group would introduce new matter into the application. The report is established as if such amendment had not been made.

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

D5 discloses glucopyranose derivatives of formula (I) useful in the prevention and/or treatment of HIV infections, asthma, atopic dermatitis, and allergic and inflammatory disorders.

D6 discloses glucopyranose derivatives of formulae (I) useful in the treatment of HIV.

D7 discloses glucopyranose or galactopyranose derivatives of formula I or II (glucose and their use in modulating cell mediated immune responses eg for treating psoriasis, asthma, inducing tolerance to antigens).

D8 discloses glucopyranose or galactopyranose derivatives of formulae I and II with immunosuppressive and tolerogenic activity for modulating cell mediated immune responses especially inflammation eg for treating psoriasis, asthma, dermatitis.

D9 discloses mono- or di- saccharide derivatives with galactose or glucose stereochemistry.

D13 discloses a galactopyranosyl derivative as a pharmaceutical.

D14 discloses a galactopyranosyl derivative with anti-HIV activity.

D15 discloses a galactopyranosyl derivative with anti-inflammatory activity.

D16 discloses a galactopyranosyl derivative with anti-inflammatory activity.

The proviso in claim 1 excludes the stereochemistry of I to be a glucose or galactose, therefore D1, D2, D4-D9 and D13-D16 no longer anticipate the claims.

D10 discloses a moranoline derivative of formula (I) used for treating inflammation, immunopathy, viral infection and cancer. Claim 1 as amended is restricted to oxygen as the heteroatom in the ring of formula I. Therefore D10 no longer anticipates the claims.

D3 discloses compounds of Structures I-VI (see Figures 8-11) which no longer anticipate the amended claim 1.

In summary, none of D1-D10 and D13-D16 discloses all of the features of each of the independent claims. Therefore all of the claims are novel and meet the requirements of Article 33(2) PCT with regards to novelty. The subject matter of these claims is also considered not obvious and meets the requirements of Article 33(3) PCT with regards to inventive step.

**Industrial Applicability (IA)**

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.



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